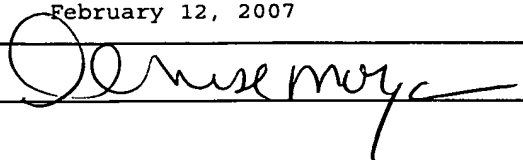
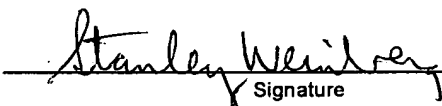
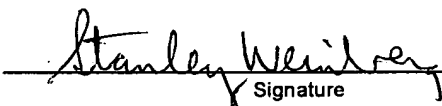
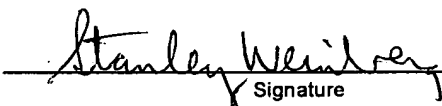


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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) BSI-010US4							
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] February 12, 2007</p> <p>on _____</p> <p>Signature <u></u></p> <p>Typed or printed name <u>Denise Morgan</u></p>		<table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%; padding: 5px;">Application Number 09/977,826</td><td style="width: 50%; padding: 5px;">Filed 10/15/2001</td></tr><tr><td colspan="2" style="padding: 5px;">First Named Inventor George Goicoechea</td></tr><tr><td style="padding: 5px;">Art Unit 3738</td><td style="padding: 5px;">Examiner William H. Matthews</td></tr></table>		Application Number 09/977,826	Filed 10/15/2001	First Named Inventor George Goicoechea		Art Unit 3738	Examiner William H. Matthews
Application Number 09/977,826	Filed 10/15/2001								
First Named Inventor George Goicoechea									
Art Unit 3738	Examiner William H. Matthews								
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <table style="width: 100%;"><tr><td style="width: 50%; vertical-align: top;"><p><input type="checkbox"/> applicant/inventor.</p><p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p><p><input checked="" type="checkbox"/> attorney or agent of record. 25,276 Registration number _____</p><p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p></td><td style="width: 50%; vertical-align: top; padding-top: 20px;"><p style="text-align: center;"><u></u> Signature Stanley Weinberg</p><p style="text-align: center;">_____ Typed or printed name</p><p style="text-align: center;">610-407-0700 Telephone number</p><p style="text-align: center;">02/12/2007 Date</p></td></tr></table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input type="checkbox"/> *Total of _____ forms are submitted.</p>				<p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. 25,276 Registration number _____</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p>	<p style="text-align: center;"><u></u> Signature Stanley Weinberg</p> <p style="text-align: center;">_____ Typed or printed name</p> <p style="text-align: center;">610-407-0700 Telephone number</p> <p style="text-align: center;">02/12/2007 Date</p>				
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This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Reasons For Review

The issues raised for purposes of this Pre-Appeal Request For Review are limited to the rejections of independent claims 54 and 56.

Claim 54

Claim 54 has been alternatively rejected as anticipated by Cragg (U.S. Patent No. 5,405,377); Fontaine (U.S. Patent No. 5,370,683); Wolff (U.S. Patent No. 5,104,404); and Furui (JP 4-25755) under various subsections of 35 U.S.C. § 102.

The following recitation is relevant to the rejections of claim 54 based on Cragg and Fontaine:

each of said hoops oriented in a plane substantially perpendicular to the longitudinal axis of the stent.

Page 2, ¶3 of the Office Action (incorporating by reference pp. 2-3, ¶¶3, 4 of the December 27, 2005 Office Action) states that Applicants' specification does not define the scope of "substantially perpendicular" or define that term to mean "perpendicular." Then, instead of relying on Applicants' disclosure to construe the term "substantially perpendicular," the Office Action relies solely on a general dictionary to define "substantial" as "being largely but not wholly that which is specified" and, in ¶3 of the incorporated Office Action, expands upon that definition and concludes that

the broadest reasonable interpretation [of "substantially perpendicular"] may include at least 90, 80, 70 or 60 degrees from the longitudinal axis.

When read in view of the claim rejections, this is not a reasonable interpretation of the term "substantially perpendicular" in claim 54 because it is based solely upon a general dictionary and ignores the meaning of that term in the important context of Applicants' disclosure.

In re Johnston, 435 F.3d 1381, 1384 (Fed. Cir. 2006) (an appeal from the BPAI) states that "dictionary definitions must give way to the meaning imparted by the specification." (emphasis added). Applicants have previously brought *Johnston* to the Examiner's attention. In response, para. 4, p.2 of the Office Action incorrectly interprets *Johnston* as allowing the Examiner discretion to use a general dictionary definition in the first instance, stating that a general dictionary definition may give way to the specification. But when the general dictionary definition relied upon in the Office Action "gives way" to Applicants' disclosure as required by *Johnston*, claim 54 as properly construed is allowable over the cited prior art.

Dictionary definitions must give way because "the specification. . . is the single best guide to the meaning of a disputed term. . . . The specification is, thus, the primary basis for construing the claims." *Phillips v. AWH Industries*, 415 F.3d 1303, 1315 (Fed. Cir. 2005), *cert. denied*, 164 L.Ed.2d 49 (2006) (citations and internal quotations omitted). *Accord*, *MBO Laboratories, Inc. v. Becton, Dickinson & Co.*, No. 2006-1062, *Slip op. at p. 8* (Fed. Cir. 1/24/07). Applicants have previously provided a copy of *Phillips* to the Examiner. Because dictionary definitions "do not necessarily reflect the inventor's goal of distinctly setting forth his invention as a person of ordinary skill in that particular art would understand it," "[a] claim should not rise or fall based upon the preferences of a particular dictionary editor." *Phillips*, 415 F.3d at 1322.

[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.

Phillips, 415 F.3d at 1313 (citations omitted) (emphasis added).

Applicants, persons of ordinary skill in the art, have described their invention in the specification, figures, and claims in a way that would be understood by one of ordinary skill in the art. Claim 54 must be interpreted in a way that is consistent with the specification and figures rather than based solely on a general dictionary definition. Therefore, claim 54 must be evaluated based upon Applicants' entire disclosure and certainly should not be evaluated based on a dictionary definition that contradicts Applicants' specification and figures.

It is significant in this matter that Cragg and Fontaine disclose helical configurations. See Cragg, col. 1, lines 57, 64; col. 2, line 44. Fontaine describes some hoops as wrapped in a spiral (col. 4, lines 13-15) and having a spiral shape (col. 7, lines 55-59).

Applicants expressly distinguished their configuration as claimed in claim 54 from the helical configuration of EP-A-0556850 (the European patent corresponding to the cited U.S. Cragg reference) as an alternative to Cragg's helical configuration:

In some embodiments the wire may have a helical configuration as disclosed in EP-A-0556850. Alternatively, the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent.

(p. 9, lines 13-19) (emphasis added).

Applicants' Figs. 1A, 1B, 2A, 2B, 3, 4A, 5-7, and 15-20 illustrate the "substantially perpendicular" embodiment in which the hoops do not form a helical configuration. The specification explains how the hoops of this embodiment are substantially perpendicular to the longitudinal axis of the stent. See, e.g., page 9, lines 13-19 ("the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent"); page 23, lines 20-23 ("the circumference of each hoop is substantially perpendicular to the longitudinal axis of the mandrel"). Furthermore, Applicants' specification as quoted above, distinguishes helical configurations from a "substantially perpendicular" configuration. Applicants' specification thus excludes helical configurations from the meaning of "substantially perpendicular." Therefore, the recitation in claim 54 that "hoops [are] oriented in a plane substantially perpendicular to the longitudinal axis of the stent" is not anticipated by references disclosing helical stents.

In summary, the Office Action is legally deficient because it relies solely upon a general dictionary definition without regard to Applicants' specification and figures. It is also legally deficient because it uses that general dictionary definition to erroneously construe claim 54 to encompass a configuration (a helical configuration) that Applicants' specification excluded from the claim.

The following recitation is relevant to the rejections of claim 54 based upon Furui and Wolff:

means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop.

Neither the current Office Action nor the incorporated Office Action contends that Applicants' disclosure fails to define the term "juxtaposed" as used in claim 54. Nevertheless, the Furui rejection of claim 54 (para. 7, p.4 of the incorporated Office Action) uses a general dictionary to define "juxtaposed" as "side by side" and "synonymous with adjacent and does not imply contact." The current Office Action then apparently gives controlling weight to this general dictionary definition of "juxtaposed." This reliance on the general dictionary definition gives primacy to the general dictionary definition and relegates Applicants' disclosure to secondary status. This analysis directly contradicts *MBO Laboratories, Johnston, and Phillips*. The general dictionary definition must give way to Applicants' specification and figures.

Applicants' specification, together with the embodiments depicted in the figures, explains and illustrates the meaning of "juxtaposed." For example, page 10, lines 18-20 explains that an apex of the sinuous wire in one hoop is secured "to a

juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors." Page 20, lines 1-4 explains that Figs. 4(b)-4(f) illustrate means for securing juxtaposed apices. Other passages in the specification, depicted in referenced figures, illustrate the meaning of "juxtaposed." See, e.g., page 25, lines 4, 7, 10 and Fig. 4(a); page 25, lines 14 and 17, referring to Figs. 4(b) and 4(c), respectively; page 26, lines 8, 16, describing features shown at least in Figs. 1B, 2A, 3; page 29, line 20 describing juxtaposed apices shown at least in Fig. 1B. The juxtaposed nature of Applicants' apices is also shown in Figs. 1A, 2B, 3, and 5-7.

The term "juxtaposed" must be construed with reference to Applicants' specification, and the general dictionary definition of "juxtaposed" must give way to Applicants' specification and figures when construing claim 54. Based on Applicants' specification, one skilled in the art would interpret "juxtaposed" to mean apices positioned in such a way that each hoop formed by the apices is supported by its neighbors. Page 10, lines 18-20.

Furui (translation provided September 29, 2005) does not show juxtaposed apices as defined by Applicants' specification and figures. Instead, Furui discloses a stent structure in which separate wires (item 6 in the translation) are interposed between the valleys of one wave-shaped ring and the peaks of the other wave-shaped ring to connect the valleys to the peaks. (Page 3, third-to-last paragraph of translation.) This structure is intended to prevent the stent from closing up when placed in a bent part of a blood vessel. (Page 4, second-to-last paragraph of translation.)

The Wolff rejection of claim 54 apparently relies on the same general dictionary definition of "juxtaposed." In contrast to a meaning of the term "juxtaposed" properly based on Applicants' disclosure, Wolff shows a hinge 14 that is interposed between ends of stent segments 12 to maintain spacing between adjacent segments (col. 1, lines 45-52). These hinge 14 components act as a bridge separating the spaced stent segments. (Column 3, lines 55-62.)

Claim 56

Claim 56, rejected under § 112, first paragraph, recites, in part:

the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

Para. 6, p. 3 of the present Office Action states

Claims 56-57 recite "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member" which is not disclosed in the specification. The

specification only provides support for the phrase "substantially perpendicular." (emphasis in original)

Para. 2, p. 2 of the present Office Action also states that the specification

does not provide support for the limitation "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member." The specification only provides support for "substantially perpendicular." (emphasis in original)

It is respectfully submitted that Applicants' specification clearly supports an embodiment in which each hoop is perpendicular.

For example, page 68, lines 7-8 (Abstract) refers to "an endoluminal stent having perpendicular hoop members." (emphasis added) Also, page 44, lines 19-23 describes axially aligned stent segments

each of the requests [sic] comprising one or more adjacent hoops, perpendicular to a common axis. . . . (emphasis added)

The specification therefore has support for "perpendicular" without the term "substantially."

As indicated above, page 68, lines 7-8 refers to "an endoluminal stent having perpendicular hoop members." This phrase refers to "hoop members," rather than a single hoop member. Also, page 44, lines 19-23 states that "each" of the stent segments comprises one or more adjacent hoops that are perpendicular to a common axis. Finally, the figures illustrate embodiments in which all hoops are oriented in this manner. The application therefore has support for "each" hoop having vertices that lie in a common plane perpendicular to the longitudinal axis.

Conclusion

In view of the foregoing, it is respectfully submitted that the rejections of claims 54 and 56 are legally deficient and should be withdrawn. A Notice of Allowance is therefore respectfully requested.

Alternatively, it is submitted that the rejection should be re-evaluated and a new Office Action should be issued that is consistent with recent legal requirements of the U.S. Court of Appeals for the Federal Circuit.